

## Plain Language: The CVM VFD regulation

The Center for Veterinary Medicine is the first Center within the Food and Drug Administration to publish a regulation using the “Plain Language” question and answer format in the codified section. Our proposed rule implementing the Veterinary Feed Directive (VFD) portion of the Animal Drug Availability Act of 1996 published in the Federal Register on July 2, 1999.

### What got CVM started with Plain Language?

- The President’s Memorandum for the Heads of Executive Departments and Agencies on “Plain Language in Government Writing” issued on June 1, 1998. This memo required that any proposed and final rulemakings published in the Federal Register after January 1, 1999 be in Plain Language (unless the original proposal had published before January 1, 1999). We expected the proposed rule on VFDs to publish after January 1, 1999, so we knew we needed to write it in Plain Language.
- We observed that it was mainly scientists and lawyers who read and interpret our regulations for others in the regulated industries. This resulted in documents that were very technical in nature and not necessarily understandable.
- An increasing number of CVM’s regulations are not intended for regulatory specialists, but rather for veterinarians, the feed industry, and animal producers.
- The Small Business Regulatory Enforcement Fairness Act of 1996 requires federal agencies to publish a simplified interpretation of all major regulations.
- These factors suggested an obvious need for the use of simplified language so the average citizen could read, understand, and follow our regulations.

### How did we get started?

The Center’s Policy and Regulations Team discussed the need for clearer writing in CVM documents. We raised the idea of drafting a regulation in Plain Language and asked for volunteers. Ron Scherzberg was eager to try with his in-process draft VFD regulation. Surfing the Internet, he found a wealth of guidance including **plainlanguage.gov**, a site sponsored by Vice President Gore’s National Partnership for Reinventing Government (NPR). In addition, all CVM Policy and Regulations Team members attended Plain Language training.

### How did we write this regulation in Plain Language?

- ✓ We began by defining our audience and deciding on the most useful plain language tools and techniques. We did not write the proposed rule for other government employees or lawyers. We wrote it for those we regulate:
  - veterinarians
  - members of the animal feed industry

animal producers, and  
members of the pharmaceutical industry

- ✓ We used a question and answer format to explain the requirements, i.e., §558.6 (c) *"What are the VFD recordkeeping requirements?"*
- ✓ We used personal pronouns in the regulation (such as "we" and "you").
- ✓ We used the more mandatory "must" rather than "shall" for the requirements, i.e., §558.6 (d)(1) *"The distributor **must** notify the FDA only once, by letter, that it intends to distribute animal feed containing a VFD drug."*
- ✓ We used simpler, more straightforward language.
- ✓ We tried to streamline the regulation by removing unnecessary language, and using short sentences and the active voice.

### **How did CVM deal with roadblocks and challenges?**

We initially met with some resistance, because the regulation in plain language did not look like what people were accustomed to seeing. Once we explained what we were doing and the strong Presidential mandate for the use of plain language, we gained support from those who had previously been skeptical.

### **What are CVM's next steps?**

We plan to use plain language in future regulations, when it is appropriate.

### **Who in CVM can help others get started?**

You can contact Ron Scherzberg at 301-827-0143 or via e-mail.